

# Congress of the United States

Washington, DC 20515

March 24, 2023

The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201  
The Honorable Robert M. Califf  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

RE: Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions To Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (Docket Number FDA-2015-D-1211)

Dear Secretary Becerra and Commissioner Califf,

We, the undersigned members of the U.S. House of Representatives, write to express our support for the proposed individual risk-based questionnaire for potential blood donors. Following almost four decades of a discriminatory deferral policy for men who have sex with men (MSM), dating back to the darkest days of the HIV/AIDS Crisis of the '80s and '90s, we acknowledge this important step to create guidance that screens all people for blood donations based on the science of virus transmission rather than a person's sexuality or how they identify.

We commend the impact that this draft guidance would have on advancing the rights of our LGBTQI+ constituents. For too long, many members of the LGBTQI+ community have been barred or deferred from donating blood simply because of who they are and who they have sex with, regardless of the risk of virus transmission. This discrimination, while always harmful, took on additional significance following violence against the community, including the 2016 tragedy at Pulse nightclub in Orlando, FL. At a moment when there was an urgent need for blood donations, many members of the LGBTQI+ community were unable to donate blood to help members of their own community. This draft guidance would reverse the blanket restrictions that have impacted many members of the community.

Further, we commend the FDA on their efforts to base this decision on science and real-world data. This update follows similar blood donation screening changes in the United Kingdom in 2021, France in 2022, and Canada in 2022.<sup>1,2,3</sup> It reflects FDA analysis of numerous data sources, including data from the UK and Canada, and the FDA-funded Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) Study. The

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<sup>1</sup> Health Canada, "Regulatory Decision Summary for CHANGE IN BLOOD DONOR DEFERRAL CRITERIA FOR RISK-BASED SEXUAL BEHAVIOUR CRITERIA," April 28, 2022, <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-detail.php?lang=en&linkID=RDS00946>.

<sup>2</sup> Véran, Olivier, "Évolution des conditions d'accès au don du sang," January 11, 2022, <https://sante.gouv.fr/archives/archives-presse/archives-communiqués-de-presse/article/evolution-des-conditions-d-acces-au-don-du-sang>.

<sup>3</sup> National Health Service Blood and Transplant, "Can donor selection policy move from a population-based donor selection policy to one based on a more individualised risk assessment? Conclusions from the For the Assessment of Individualised Risk (FAIR) group," December 2020, [https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/21001/fair\\_sabto\\_20201211.pdf](https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/21001/fair_sabto_20201211.pdf).

ADVANCE Study is currently unpublished, and we look forward to working with the FDA as the results of this research become available.

While the framework for the deferral policy is a substantial improvement, we recognize that the draft guidance would still disproportionately prevent some members of the LGBTQI+ community, and especially MSM, from donating blood. We hope that continued analysis of the ADVANCE Study and further research will allow for updates to expand the opportunity for blood donation to more members of the LGBTQI+ community.

We particularly hope that further analysis of the ADVANCE Study, new data, and improvements in testing and pathogen reduction technologies will support changes to the guidance's current deferral for people taking pre-exposure prophylaxis, or PrEP. While the draft guidance removes some long-standing barriers to blood donation, the restriction for those taking PrEP may curb some of the positive impacts of this update. As you know, PrEP is approximately 99 percent effective in preventing HIV transmission through sex.<sup>4</sup> We understand that the deferral for people taking PrEP is based on available data that demonstrates that use of PrEP may delay detection of HIV in screening tests for blood donations.<sup>5,6</sup> We hope that with additional data and new technological developments, the FDA will be able to amend the scope of this restriction while continuing to ensure the safety of the blood supply. Looking forward, we urge the FDA to continue working together with Congress on developing the next generation of screening and pathogen reduction technologies.

Given this restriction, we also urge the FDA, CDC, and other federal agencies to continue to emphasize the integral role that PrEP plays in the effort to end the HIV epidemic, including throughout the implementation of this new guidance.<sup>7</sup> People who use PrEP are taking steps to safeguard their health and prevent HIV infection. It is our hope that the implementation of this guidance will not stigmatize nor discourage continued use of PrEP.

Lastly, we strongly urge the FDA and HHS to take the necessary steps to educate newly eligible donors, especially members of the LGBTQI+ community, about the new guidance and the importance of blood donation.

For too long, the federal government has dictated who can and cannot give blood based on outdated and disproven fears. Instead, we must follow the science and evidence-based data in our blood donation and public information efforts. By making this proposed change, the federal government will begin to break down stigma and increase our capacity to save lives. We encourage the FDA to finalize and implement the draft guidance expeditiously following the public comment period.

Sincerely,


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<sup>4</sup> Centers for Disease Control and Prevention (CDC), "Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV," Last reviewed June 17, 2022, <https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html>.

<sup>5</sup> Seed, Clive R., Claire E. Styles, Veronica C. Hoad, Hung Yang, Michael J. Thomas, and Iain B. Gosbell, "Effect of HIV pre-exposure prophylaxis (PrEP) on detection of early infection and its impact on the appropriate post-PrEP deferral period," *Vox Sanguinis* 116, no. 4 (2021): 379-387, <https://doi.org/10.1111/vox.13011>

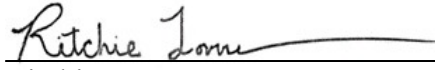
<sup>6</sup> Bares, Sara H., and Kimberly K. Scarsi, "A new paradigm for antiretroviral delivery: long-acting cabotegravir and rilpivirine for the treatment and prevention of HIV," *Current Opinion in HIV and AIDS* 17, no. 1 (2022): 22, <https://doi.org/10.1097%2FCOH.0000000000000708>.

<sup>7</sup> CDC, "Ending the HIV Epidemic in the U.S. (EHE)," Last reviewed June 7, 2022, <https://www.cdc.gov/endhiv/index.html>.



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Mike Quigley  
Member of Congress



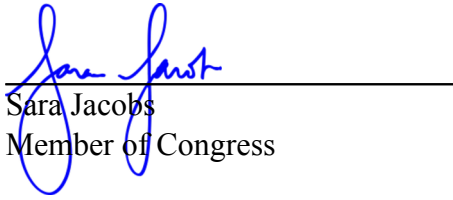
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Ritchie Torres  
Member of Congress




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Eric Sorensen  
Member of Congress



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Sara Jacobs  
Member of Congress



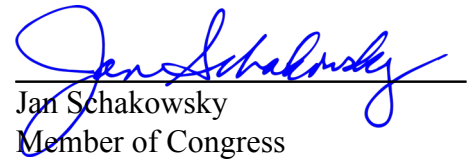
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Adam Smith  
Member of Congress



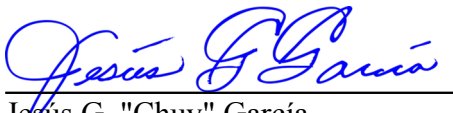
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Danny K. Davis  
Member of Congress



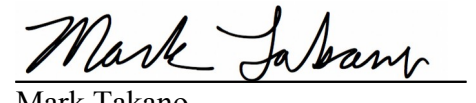
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Jan Schakowsky  
Member of Congress




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Jesús G. "Chuy" García  
Member of Congress



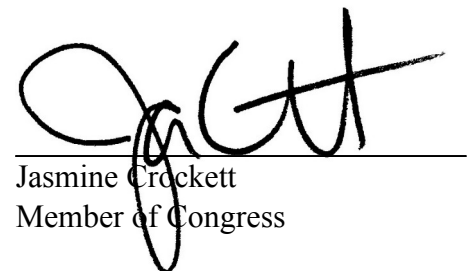
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Mark Takano  
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Mark Pocan  
Member of Congress

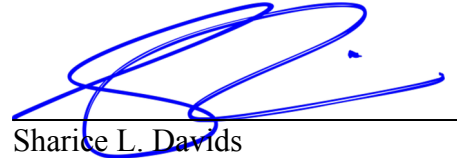


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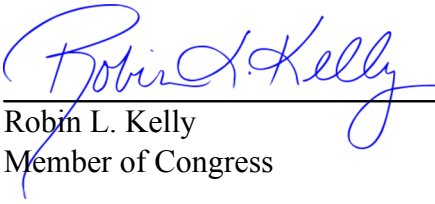
Jasmine Crockett  
Member of Congress



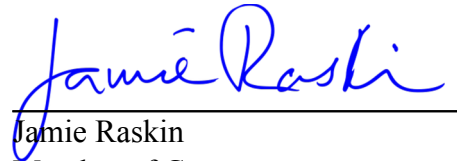
Adriano Espaillat  
Member of Congress



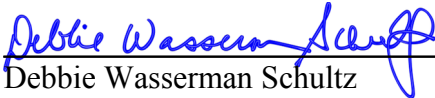
Sharice L. Davids  
Member of Congress



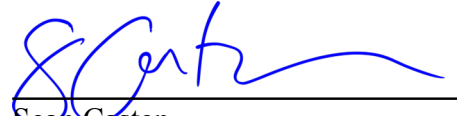
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Member of Congress



Jamie Raskin  
Member of Congress



Debbie Wasserman Schultz  
Member of Congress



Sean Casten  
Member of Congress



Raul Ruiz, M.D.  
Member of Congress



Paul D. Tonko  
Member of Congress



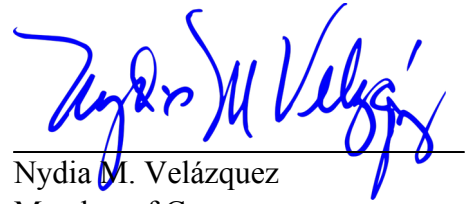
Eleanor Holmes Norton  
Member of Congress



Jil Tokuda  
Member of Congress

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Rick Larsen  
Member of Congress

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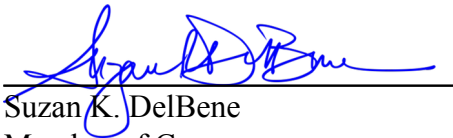
Nydia M. Velázquez  
Member of Congress

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Gwen S. Moore  
Member of Congress

A handwritten signature in blue ink, reading "Brian Higgins", written over a horizontal line.

Brian Higgins  
Member of Congress

A handwritten signature in blue ink, reading "Suzan K. DelBene", written over a horizontal line.

Suzan K. DelBene  
Member of Congress